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April 3, 2003

Mr. Stuart Shapiro  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

Dear Mr. Shapiro:

Re: Docket No. 02N-0278

This letter is in response to the Food and Drug Administration's (FDA) request for comments on the rules proposed under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the *Bioterrorism Act*).

The Government of Alberta supports the FDA's stated objective of countering bioterrorism while meeting the US' international trade obligations. However, the Government of Alberta is concerned that elements of the proposed rules are more trade restrictive than is necessary to achieve the FDA's objectives.

Canada and the US exchange large volumes of food every day, and much of this trade involves just-in-time delivery and same day ordering. In order to maintain the secure and efficient trade environment Canada and the US have put in place programs such as the Ridge-Manley Smart Border Plan. In addition, many Canadian exporters are enrolled in programs such as the Customs-Trade Partnership Against Terrorism (C-TPAT) and Free and Secure Trade (FAST), which reduce risk associated with Canadian food exports to the US. The Government of Alberta believes that any rules formulated under the *Bioterrorism Act* must take into account this trading environment, which developed over several decades.

With this context in mind the Government of Alberta wishes to make the following comments on the prior notice requirements of the proposed regulation.

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### Time of Notification

Section 307 of the *Bioterrorism Act* requires prior notice of imported food shipments to the US. In its proposed rule the FDA specifies that advance notice of a food shipment be submitted no later than noon of the calendar day before the day the article of food will arrive at a specific border crossing point. This requirement appears to be incompatible with the large volume of Canada-US trade that involves just-in-time delivery and same day ordering. Many Canadian food production and processing facilities are located near the Canada-US border and are able to load and deliver shipments to the US in less than 24 hours. Given this unique relationship between Canada and the US, the Government of Alberta suggests that the FDA consider allowing prior notice to be received as late as four hours before arrival.

Food shipments from Canada to the US are carried on a variety of modes such as rail, truck, aircraft and ship. The ability to estimate time of arrival at a specific border entry point differs across these modes of transportation. As an alternative to a single time of advance notification for all modes of transportation, the Government of Alberta suggests that the times required for advance notice vary according to the mode of transport.

### Persons Authorized to Submit Notification

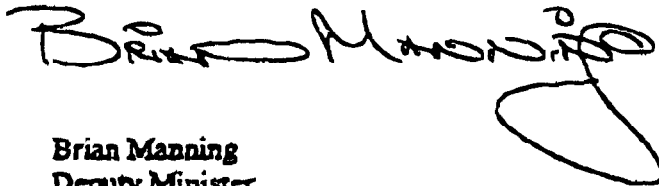
The proposed regulation authorizes purchasers and importers of food (or their agents), who reside or maintain a business in the US to provide prior notice. An importer may know what they have ordered and an approximate delivery time at their premises but is less likely to know when a food shipment will reach the border entry point. Exporters are more likely to have the information required by the FDA. The Government of Alberta notes that the *Bioterrorism Act* does not specify who should submit prior notice of a food shipment and therefore suggests that exporters be authorized to submit prior notice.

### Low Risk Shipments

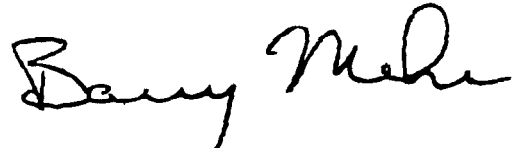
Finally, the Government of Alberta recommends that exporters who have reduced the risk of bioterrorism by participating in US Customs programs such as C-TPAT and FAST be exempted from the requirement to provide prior notice.

The Government of Alberta offers these comments on the proposed rule and urges the FDA to develop a regulation that reflects the highly integrated, rapid and largely low-risk nature of Canada-US trade in food products.

Sincerely,



Brian Manning  
Deputy Minister  
Alberta Agriculture, Food  
Rural Development



Barry Mehr  
Deputy Minister  
Economic Development.

cc: Honourable Shirley McClellan  
Deputy Premier and Minister of Alberta Agriculture,  
Food and Rural Development

Honourable Halvar Jonson  
Minister of International and Intergovernmental Relations

Honourable Mark Norris  
Minister of Economic Development

Gerry Bourdeau, Deputy Minister of  
International and Intergovernmental Relations

Leonard Edwards, Deputy Minister of  
International Trade, Department of Foreign Affairs and International Trade

Samy Watson, Deputy Minister  
Agriculture and Agri-Food Canada



**Policy Secretariat**  
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## Fax Transmittal Sheet

To: Mr. Stuart Shapiro,  
Dockets Management Branch (HFA-305)  
(301) 827-6870

Fax #: \_\_\_\_\_

Date: April 3, 2003

#of Pages (incl cover sheet): 4

Subject: Letter attached

From:

Please see attached letter

If you have trouble  
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please call Judy at:  
(780) 422-2086